

REMARKS

A check for \$450 for a two-month extension of time accompanies this response. Any fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 06-1050. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

The specification is amended herein to correct minor typographical errors. No new matter is added.

Claims 1-17, 23-26, 30-52, 55, 57-63, 98 and 100-107 are pending. Claim 99 is cancelled herein without prejudice or disclaimer. Claims 1, 6, 9, 30, 34-37, 40-42, 46, 57, 59-61, 98, 105 and 107 are amended herein. Claims 1, 42 and 98 are amended herein to correct an inadvertent typographical error in Formulae III and IV. Formulae III and IV are amended to replace the double-bonded Y substituent with a single-bonded R¹¹ substituent. Basis for the amendment is found throughout the specification (for example, see page 12, lines 1-5 and original claim 1). Claims 1, 42 and 98 also are amended to cancel Formulae V through VIII, which are non-elected subject matter. Applicant reserves the right to file divisional application(s) to the cancelled subject matter. Claims 1, 42 and 98 are further amended to more distinctly claim the subject matter by separating out the definitions for substituents R³ through R⁸. Basis for the amendment is found throughout the specification (e.g., see pages 16-24). Claims 1, 30, 34, 35, 37, 42, 57, 59, 61, 98 and 105 are amended to delete the embodiments where R⁴ and R⁶ or R⁶ and R⁸ taken together form a heterocyclic ring. Claim 6 is amended to correct a minor typographical error. Claims 9 and 36 are amended to more distinctly claim the subject matter to recite that the alkyl group is substituted.

Claims 40 and 41 are amended to delete non-elected subject matter. Applicant reserves the right to file divisional application(s) to the cancelled subject matter. Claims 40 and 41 also are amended to more distinctly claim the subject matter by replacing the recitation "trifluoroethyl" with the recitation "2,2,2-trifluoroethyl." Basis for the amendment is found throughout the specification (for example, see page 54, lines 19-20; page 56, lines 12-13; page 56, lines 20-22; and page 59, lines 23-25). Claims 46 and 60 are amended to more distinctly claim the subject matter by deleting the recitation "hydrogen."

No new matter is added.

THE REJECTION OF CLAIMS 9-11, 36-39, 46, 47, 60-63 AND 99 UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 9-11, 36-39, 46, 47, 60-63 and 99 are rejected as allegedly failing to particularly point out and distinctly claim the subject matter for which protection is being sought.

Claims 9 and 36

Claims 9 and 36 and claims dependent thereon are rejected because substituent R¹ recites "unsubstituted alkyl," which allegedly has no antecedent basis in base claim 1. Claims 9 and 36 are amended to conform the definition of substituent R¹ to the definition of R¹ recited in claim 1. Applicant respectfully submits that the rejection is rendered moot in light of the amendment of claims 9 and 36 herein, which deletes the recitation "unsubstituted alkyl" from the definition of substituent R¹ in claims 9 and 36.

Claims 46 and 60

Claims 46 and 60 and claims dependent thereon are rejected because substituent R² recites "hydrogen," which allegedly has no antecedent basis in base claim 42. Claims 46 and 60 are amended to conform the definition of substituent R² to the definition for R² recited in claim 42. Applicant respectfully submits that the rejection is rendered moot in light of the amendment of claims 46 and 60 herein, which deletes the recitation "hydrogen" from the definition of substituent R² in claims 46 and 60.

Claim 99

Claim 99 is rejected because there allegedly is no basis for the recitation "carrier" in the base claim 98. Applicant respectfully submits that the rejection is rendered moot in light of the cancellation of claim 99 herein.

THE REJECTION OF CLAIMS 1-17, 23-26, 30-39, 42-52, 55, 57-63 AND 98-107 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1-17, 23-26, 30-39, 42-52, 55, 57-63 and 98-107 are rejected as allegedly failing to comply with the written description requirement. The Examiner alleges that the claims include subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor as the time the application was filed has possession of the claimed subject matter. The Examiner provides several bases for rejection, which are discussed in turn below. This rejection is respectfully traversed.

RELEVANT LAW

The purpose behind the written description requirement is to ensure that the patent applicant had possession of the claimed subject matter at the time of filing of the application *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). The manner in which the specification meets the requirement is not material; it may be met by either an express or an implicit disclosure.

35 U.S.C. §112 requires a written description of the invention. This requirement is distinct from and not coterminous with the enablement requirement:

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed." *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563-64, 19 USPQ2d at 1117.

The issue with respect to 35 U.S.C. §112, first paragraph, adequate written description has been stated as:

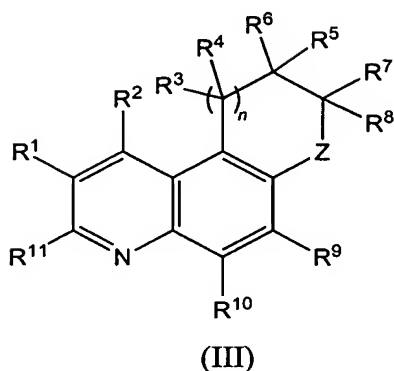
[d]oes the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound [claimed embodiment] *Vas-Cath, Inc. v. Mahurkar*, at 1115, quoting *In re Ruschig*, 390 F.2d 1990, at 995-996, 154 USPQ 118 at 123 (CCPA 1967).

A specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, *i.e.*, whatever is now claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ.2d 1111, 1117 (Fed. Cir. 1991).

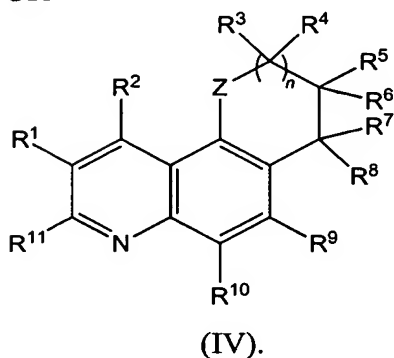
ANALYSIS

1. Formulae III and IV

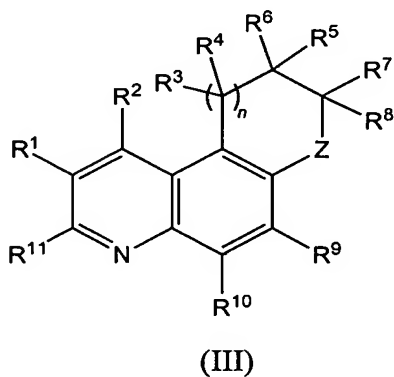
Claims 1 and 42 are rejected because it is alleged that Formulae III and IV are not described in the specification. Claims 1 and 42 are amended herein to replace the Y substituent with R¹¹ to correct the inadvertent typographical error introduced in Formulae III and IV. Basis for compounds of Formulae III and IV is found throughout the specification. For example, see page 12, lines 1-5, which sets forth Formulae III and IV as:



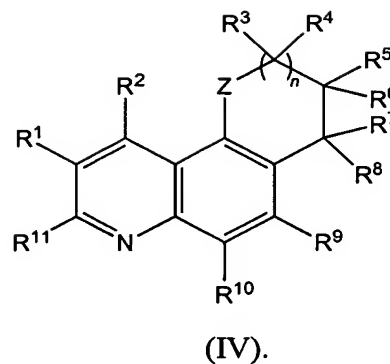
OR



In addition, original claim 1 sets forth Formulae III and IV as:



and



Thus, the specification provides basis for compounds of Formulae III and IV. Applicant respectfully requests reconsideration and withdrawal of the rejection.

2. "Substituted Alkyl"

Claims 1 and 42 are rejected because the specification allegedly fails to describe a compound where R^1 and/or R^2 is a "substituted alkyl." The applicant respectfully disagrees. The specification teaches that the alkyl group of substituents R^1 and R^2 may be optionally substituted. For example, see page 5, lines 2-8, which recites:

R^1 is selected from among hydrogen, F, Cl, Br, I, NO_2 , OR^{12} , SR^{12} , SOR^{12} , SO_2R^{12} , $\text{NR}^{12}\text{R}^{13}$, $\text{C}_1\text{-C}_8$ alkyl, $\text{C}_1\text{-C}_8$ haloalkyl and $\text{C}_1\text{-C}_8$ heteroalkyl, wherein **the alkyl, haloalkyl and heteroalkyl groups are optionally substituted;**

R^2 is selected from among F, Cl, Br, I, CF_3 , CHF_2 , CH_2F , CF_2Cl , CN, $\text{CF}_2\text{OR}^{12}$, $\text{CH}_2\text{OR}^{12}$, OR^{12} , SR^{12} , SOR^{12} , SO_2R^{12} , $\text{NR}^{12}\text{R}^{13}$, $\text{C}_1\text{-C}_8$ alkyl, $\text{C}_1\text{-C}_8$ haloalkyl, $\text{C}_1\text{-C}_8$ heteroalkyl, $\text{C}_2\text{-C}_8$ alkenyl and $\text{C}_2\text{-C}_8$ alkynyl, wherein **the alkyl, haloalkyl, heteroalkyl, alkenyl and alkynyl groups are optionally substituted;** [emphasis added].

The specification states, on page 10, line 10, that “ ‘optionally substituted’ groups may be substituted or unsubstituted.” Thus, the recitation “optionally substituted” means “substituted or unsubstituted” throughout the specification. Hence, the specification discloses as a genus compounds with substituents, such as alkyl, haloalkyl and heteroalkyl groups, that are substituted or unsubstituted. For example, the definition for R^1 equivalently can be recited:

R^1 is selected from among hydrogen, F, Cl, Br, I, NO_2 , OR^{12} , SR^{12} , SOR^{12} , SO_2R^{12} , $\text{NR}^{12}\text{R}^{13}$, substituted or unsubstituted $\text{C}_1\text{-C}_8$ alkyl, substituted or unsubstituted $\text{C}_1\text{-C}_8$ haloalkyl and substituted or unsubstituted $\text{C}_1\text{-C}_8$ heteroalkyl;

Therefore, the specification provides basis for the recitation “substituted alkyl” for the descriptions of substituents R^1 and R^2 in claims 1 and 42. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

3. Claim 98

Claim 98 is rejected because the specification allegedly fails to describe a compound where R^2 is an alkyl selected from among ethyl, *n*-propyl, isopropyl, *n*-butyl, isobutyl, *sec*-butyl, *tert*-butyl, *tert*-amyl, pentyl, hexyl, heptyl and octyl. Without addressing the propriety of the rejection, in the interest of advancing the application to allowance, it is respectfully submitted that this rejection is rendered moot in light of the amendment of claim 98 herein.

THE REJECTION OF CLAIMS 1-17, 23-26, 30-39, 42-52, 55, 57-63 AND 98-107 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1-17, 23-26, 30-39, 42-52, 55, 57-63 and 98-107 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly being broader than the enabling disclosure because the specification allegedly does not enable a person skilled in the art to make and use compounds commensurate in scope with the claims. The Examiner alleges that the specification does not provide enablement for (a) compounds where R^4 and R^6 together or R^6 and R^8 together form a heterocyclic ring or (b) compounds where the adjacent R^3 - R^8 substituents are all optionally substituted aryl or heteroaryl. This rejection is respectfully traversed.

RELEVANT LAW

The test of enablement is whether one skilled in the art can make and use what is claimed based upon the disclosure in the application and information known to those of skill in the art without undue experimentation. *United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988). A certain amount of experimentation is permissible as long as it is not undue. A considerable amount of experimentation is permissible, particularly if it is routine experimentation. The amount of experimentation that is permissible depends upon a number of factors, which include: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, and the breadth of the claims. *See, Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int'f 1986); see also *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988).

A patent application need not teach, and preferably omits, what is well known in the art. *Spectra-Physics, Inc. v. Coherent, Inc.*, 3 USPQ2d 1737 (Fed. Cir. 1987). Indeed, "not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted." *In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q.2d 1331, 1332. Showing every combination of substituents is unnecessary. The law is clear that patent documents need not include subject matter that is known in the field of the invention and is in the prior art, for patents are written for persons experienced in the field of the invention. *See Vivid Technologies, Inc. v. American Science and Engineering, Inc.*, 200 F.3d 795, 804, 53 USPQ2d 1289, 1295 (Fed. Cir. 1999).

ANALYSIS

A. "Heterocyclic Ring"

Claims 1-17, 23-26, 30-39, 42-52, 55, 57-63 and 98-107 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly being broader than the enabling disclosure because the specification allegedly does not provide enablement for compounds where R⁴ and R⁶ together or R⁶ and R⁸ together form a heterocyclic ring. Without conceding the propriety of the rejection, in the interest of advancing this application to allowance, it is respectfully submitted that this rejection is rendered moot by the amendment of claims 1, 30, 34, 35, 37, 42, 57, 59, 61, 98 and 105 to delete the embodiments where R⁴ and R⁶ or R⁶ and R⁸ taken together form a heterocyclic ring.

B. "Adjacent R³ through R⁸ Substituents"

Claims 1-17, 23-26, 30-39, 42-52, 55, 57-63 and 98-107 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly being broader than the enabling disclosure because the specification allegedly does not provide enablement for compounds where the adjacent R³-R⁸ substituents are all optionally substituted aryl or heteroaryl. Applicant respectfully submits that as amended, the adjacent R³-R⁸ substituents of claims 1, 42 and 98 cannot all be optionally substituted aryl or heteroaryl. In pending claims 1, 42 and 98, none of R³, R⁵ nor R⁷ includes as an element in its description an optionally substituted aryl or heteroaryl. Thus, the rejection is rendered moot by the amendment of claims 1, 42 and 98 herein.

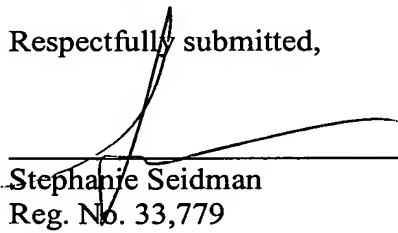
Objection to Claims 40 and 41

The Examiner objects to claims 40 and 41 as being allowable but depending from a rejected base claim. Applicant respectfully submits that claim 1 (the base claim) is in condition for allowance. Thus, applicants respectfully request that the objection to claims 40 and 41 be reconsidered and withdrawn.

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In view of the above, reconsideration and allowance is respectfully requested.

Respectfully submitted,



Stephanie Seidman
Reg. No. 33,779

Attorney Docket No. 18202-017001 / 1081

Address all correspondence to:

Stephanie Seidman
Fish & Richardson P.C.
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-5070
Facsimile: (202) 626-7796
email: seidman@fr.com